Supreme Court U.S.
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No. 01-188

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services; and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, THE 60 PLUS ASSOCIATION, and THE INTERNATIONAL PATIENT ADVOCACY ASSOC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

1. Does the federal Medicaid statute, 42 U.S.C. § 1396, *et seq.*, allow a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. May a State circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the State, to pay the State each time one of its products is subsequently sold by a retailer within the State?

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iv

INTERESTS OF *AMICI CURIAE* 1

STATEMENT OF THE CASE 3

SUMMARY OF ARGUMENT 7

ARGUMENT 8

I. MAINE'S USE OF ITS PRIOR AUTHORIZATION AUTHORITY TO AID NON-MEDICAID POPULATIONS CONFLICTS WITH, AND THUS IS PREEMPTED BY, FEDERAL MEDICAID LAW 8

II. THE MAINE RX PROGRAM VIOLATES THE COMMERCE CLAUSE 15

A. The Program Is Not Exempted from Commerce Clause Scrutiny by the Market Participant Exception 15

B. The Maine Rx Program Violates the Dormant Commerce Clause Because It Regulates Commerce Extraterritorially 21

CONCLUSION 29

TABLE OF AUTHORITIES

Cases: **Page**

Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935) 22, 24
Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986) 24
Buckman Co. v. Plaintiffs' Legal Committee 121 S. Ct. 1012 (2001) 12
California Fed. Sav. and Loan Ass'n v. Guerra, 479 U.S. 272 (1987) 10
Camps Newfound/Owatonna, Inc. v. Town of Harrison, 520 U.S. 564 (1997) 16, 17
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 9
CTS Corp. v. Dynamics Corp. of America, 481 U.S. 69 (1987) 26
Edgar v. MITE Corp., 457 U.S. 624 (1982) 25
English v. General Electric Co., 496 U.S. 72 (1990) 12
Healy v. Beer Institute, 491 U.S. 324 (1989) 16, 22, 24, 25, 26
Hughes v. Alexandria Scrap Corp., 426 U.S. 794 (1976) 16, 17, 18
Grant's Dairy--Maine, LLC v. Commissioner, 232 F.3d 8 (1st Cir. 2000) 11
Mayburg v. Secretary of Health & Human Servs., 740 F.2d 100 (1st Cir. 1983) 10
National Foreign Trade Council v. Natsios, 181 F.3d 38 (1st Cir. 1999), *aff'd*, 530 U.S. 363 (2000) 1

Page

Quill Corp. v. North Dakota, 504 U.S. 298 (1992) 27, 28
Reeves, Inc. v. Stake, 447 U.S. 429 (1980) 16, 21
South-Central Timber Development, Inc. v. Wunnicke, 467 U.S. 82 (1984) 17, 18, 20
Wash., Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549 (1987) 12
White v. Massachusetts Council of Construction Employers, Inc., 460 U.S. 204 (1983) 16- 21

Statutes and Constitutional Provisions:

U.S. Const., Commerce Clause . . . . . *passim*

42 U.S.C. § 196 13
42 U.S.C. § 1396 10
42 U.S.C. § 1396c(a)(19) 10
42 U.S.C. § 1396r-8(a)(1) 14
42 U.S.C. § 1396r-8(d)(1) 9
42 U.S.C. § 1396r-8(d)(2) 14
42 U.S.C. § 1396r-8(d)(5) 9, 14

"An Act to Establish Fairer Pricing for Prescription Drugs," 200 Me. Legis. Ch. 786 (S.P. 1026) 4
22 M.R.S.A. § 2681 4
22 M.R.S.A. § 2681(3) 4
22 M.R.S.A. § 2681(4) 4
22 M.R.S.A. § 2681(5), (6) 4
22 M.R.S.A. § 2681(7) 13

Page

Regulations:

42 C.F.R. §§ 456.702-3 10

Miscellaneous:

H.R. Rep. No. 881, 101 Cong., 2d Sess. 98 (1990) . . 14

BRIEF OF WASHINGTON LEGAL FOUNDATION, ALLIED EDUCATIONAL FOUNDATION, KIDNEY CANCER ASSOCIATION, THE SENIORS COALITION, THE 60 PLUS ASSOCIATION, AND INTERNATIONAL PATIENT ADVOCACY ASSOC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF)[1] is a non-profit public interest law and policy center with supporters in all 50 states, including many in Maine. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. To that end, WLF has appeared before numerous federal and state courts in cases raising issues arising under the dormant Commerce Clause. *See, e.g., National Foreign Trade Council v. Natsios,* 181 F.3d 38 (1st Cir. 1999), *aff'd,* 530 U.S. 363 (2000). WLF recently successfully challenged the constitutionality of Food and Drug Administration restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study,

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

The Seniors Coalition (TSC) is a non-profit, non-partisan education and issue advocacy organization that represents the interests and concerns of America's senior citizens at both the state and local levels. TSC's mission is to give America's seniors a real voice in government to enact public policies that promote and protect their quality of life and economic security. Founded in 1989, TSC has grown to nearly 4 million members; its advocacy includes a wide range of issues important to seniors, including Social Security, Medicare, long-term care, generic drug access, and tax reform.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

The International Patient Advocacy Association (IPAA) is a non-profit organization based in Bellevue, Washington. IPAA's mission is to work closely with patients, physicians, industry, researchers, and legislators to provide legal and patient advocacy, free of charge.

Amici are concerned that the Maine Rx Program, if allowed to take effect, will have long-term adverse effects on health care in this country. By interfering with the free market in pharmaceutical sales, the Program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient national market.

Amici also filed a brief in this case in support of the petition for a writ of certiorari, and when it was before the appeals court. *Amici* are filing this brief with the consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of the Case contained in Petitioner's brief.

In brief, the Pharmaceutical Research and Manufacturers of America ("PhRMA") challenges a Maine law that requires drug manufacturers to subsidize retail drug discounts to Maine residents under a new program called the "Maine Rx Program." Payment of the subsidies is (from a practical standpoint) mandatory, because the State of Maine administers the federal Medicaid program within the State (a program in which all major drug manufacturers participate), and the Maine Rx Program prescribes severe retaliation in connection with Medicaid against any manufacturer that refuses to pay the mandated subsidy. *See* Petition Appendix ("Pet. App.") 70-71.

The Maine RX Program was adopted by the state legislature in May 2000. The law, entitled "An Act to Establish Fairer Pricing for Prescription Drugs" (the "Act"), 2000 Me. Legis. Ch. 786 (S.P. 1026), is codified at 22 M.R.S.A. § 2681. The Act provides that drug manufacturers "shall enter into a rebate agreement" with the Maine Department of Human Services (the "Department") and that the agreement "must require" manufacturers to "make rebate payments to the State each calendar quarter or according to a schedule established by the department." 22 M.R.S.A. § 2681(3). The Act further requires the Department to use "best efforts" to establish rebates at a level equal to or greater than discounts obtained by the federal government in connection with its bulk purchases of prescription drugs. 22 M.R.S.A. § 2681(4). The Act further provides that pharmacists in Maine are to sell prescription drugs to Maine residents at substantially discounted prices and that money collected by the State from drug manufacturers under the Maine Rx Program is to be paid to the pharmacists in order to reimburse them for those discounts. 22 M.R.S.A. §§ 2681(5), (6).

The subsidies are required of all drug manufacturers whose products are sold in Maine, even though no drug manufacturers are based in Maine and even though very few of them sell their products to Maine wholesalers. Rather, virtually all prescription drugs that end up in Maine are sold to wholesalers or distributors in transactions that occur outside the State; the wholesalers and distributors make their own arrangements for shipment into Maine. Pet. App. 60. Moreover, as the district court recognized, the rebate program results in a reduction in the wholesale price obtained by manufacturers for each drug that is later sold in Maine, because the amount of a manufacturer's rebate is determined

by the quantity of that manufacturer's products sold in Maine. *Id.* at 66.

PhRMA filed suit against the Maine Rx Program in U.S. District Court for the District of Maine. The Complaint alleged that the Program violated the Commerce Clause of the U.S. Constitution by attempting to regulate transactions occurring outside of Maine, and violated the Supremacy Clause by requiring Maine to administer the Medicaid program in a manner that conflicts with federal law.

On October 26, 2000, the district court granted PhRMA's motion for a preliminary injunction against any efforts by Maine to enforce the payment of rebates under the Program. Pet. App. 57-72. Initially, the court rejected Maine's argument that the Maine Rx Program entailed nothing more than the exercise of power derived from Maine's role as a participant in the prescription drug market, and thus that the Program should be exempt from Commerce Clause scrutiny under the "market participation" exception. The court said that that exception does not immunize State efforts to leverage power derived from one market in which it participates (in this case, the purchase of drugs under the Medicaid program) in order to regulate a market in which it does not participate (in this case, the market for prescription drugs purchased outside of Medicaid). *Id.* at 61-64.

The court went on to find that the Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State. *Id.* at 64-66. "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." *Id.* at 65. The court

held that the Program was invalid without regard to whether the Program could be said to discriminate against out-of-staters in favor of in-staters. *Id.* at 66.

The court also held that the Program was invalid under the Supremacy Clause because it was impliedly preempted by federal Medicaid law. *Id.* at 66-70. The court found that the Program stood "as an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid," because it made it more difficult for certain drugs to be prescribed to Medicaid recipients. *Id.* at 68.

Having found that PhRMA was "overwhelming[ly]" likely to prevail on the merits and that the other relevant factors also favored PhRMA, the court granted a preliminary injunction against enforcement of the Program's rebate scheme. *Id.* at 72.

The U.S. Court of Appeals for the First Circuit reversed and vacated the preliminary injunction. *Id.* at 1-53. The appeals court initially determined that the Program was not preempted by federal law, finding "no conflict between the Maine Act and Medicaid's structure and purpose." *Id.* at 11. While noting that the Program threatens imposition of a "prior authorization" requirement on manufacturers that do not participate in the Act's price control program, the court held that the Medicaid statute does not concern itself with a State's motivation in choosing to impose such a requirement -- and thus that Maine's use of its "prior authorization" power as a club to ensure manufacturer participation does not conflict with any purpose of the Medicaid law. *Id.* at 12-13. The court said that the Program actually "furthers Medicaid's aim of providing medical services to those" otherwise unable

to meet the costs of necessary medical services but who are not poor enough to qualify for Medicaid. *Id.* at 13.

The appeals court also held that the Program did not violate the Commerce Clause. *Id.* at 17-27. As did the district court, the appeals court rejected Maine's argument that it was exempt from Commerce Clause restraints by virtue of its status as a "market participant." *Id.* at 20. The court nonetheless rejected PhRMA's Commerce Clause challenge, finding that "the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state," *Id.* at 23. The court reasoned, "Simply because the manufacturers' profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits." *Id.* The court held that whatever burdens the Program imposed on interstate commerce were not "clearly excessive" in relation to the benefits derived by Maine. *Id.* at 25-27.

On June 13, 2001, the First Circuit issued an order stating that no action could be taken on PhRMA's petition for rehearing *en banc*. Pet. App. 54-55. The court explained that -- except for Judge Torruella, who voted in favor of rehearing *en banc* -- all of the First Circuit judges in regular active service had recused themselves from the case. *Id.*

SUMMARY OF ARGUMENT

The Maine Rx Program threatens to impose prior authorization requirements on Medicaid coverage for any drug manufactured by a company that does not agree to charge substantially reduced prices to uninsured individuals. By doing so, Maine no doubt is providing a substantial cost savings to its non-Medicaid population. But at the same time,

the Program jeopardizes the health of Medicaid recipients by potentially denying them access to optimal medical care. The Medicaid statutes are intended to ensure that even those with very low incomes have access to a high level of medical care. Accordingly, the Maine Rx Program is preempted by federal law; such preemption is mandated whenever, as here, the challenged State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

The Maine RX Program should be enjoined for the additional reason that it violates the Commerce Clause. Despite Maine's assertions to the contrary, the Program can only be viewed as an effort by the State to impose price controls on wholesale drug transactions that take place entirely outside Maine. Such extraterritorial applications of State law are *per se* invalid under the Commerce Clause. Nor may Maine seek protection from the Commerce Clause by invoking the "market participant" exception, in the absence of evidence that Maine's operation of the Program was more akin to that of a market participant than to that of a government regulator.

ARGUMENT

I. MAINE'S USE OF ITS PRIOR AUTHORIZATION AUTHORITY TO AID NON-MEDICAID POPULATIONS CONFLICTS WITH, AND THUS IS PREEMPTED BY, FEDERAL MEDICAID LAW

Although the Maine Rx Program is independent of the State's administration of Medicaid, the Program uses a provision of Medicaid as a club to ensure manufacturer participation in its rebate program, the "prior authorization"

provision.[2] When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator. The Maine Rx Program threatens that all of a manufacturer's drugs will be subject to Medicaid prior authorization if the manufacturer fails to participate in the rebate program. Because all pharmaceutical manufacturers derive significant income from Medicaid and because it is well accepted that any company whose drugs are subjected to Medicaid prior authorization will suffer significant sales loss, manufacturers are, for all intents and purposes, forced to participate in the Maine Rx Program. As the district court found, the Maine Rx Program cannot realistically be deemed "voluntary." Pet. App. 70-71.

In other words, Maine is using the authority it possesses by virtue of its role as Medicaid administrator to aid individuals who are not eligible to participate in Medicaid. *Amici* believe it plain that Maine's use of its authority in that manner conflicts with federal law and thus is preempted by it. While no provision of the Medicaid law expressly forbids what Maine has done, the Maine Rx Program is impliedly preempted by federal law because it is inconsistent with Medicaid's objectives.

State law is impliedly preempted if: (1) it actually conflicts with federal law; or (2) federal law so thoroughly occupies a legislative field "as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citations omitted). State law "actually

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[2] *See* 42 U.S.C. § 1396r-8(d)(1), (5), which authorize states to impose prior authorization requirements for prescriptions paid by Medicaid, subject to certain procedural safeguards.

conflicts" with federal law "*either* because compliance with both federal law and state regulations is a physical impossibility, *or* because the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California Fed. Sav. and Loan Ass'n v. Guerra,* 479 U.S. 272, 281 (1987) (emphasis added and internal quotations omitted).

As the district court accurately noted:

> The purposes of the federal Medicaid program are straightforward: to provide medical services, including prescription drugs, 42 C.F.R. §§ 456.702-3 (West 2000), to those with medical needs who qualify under Medicaid's eligibility standards. 42 U.S.C.A. § 1396 (West 1992); *Mayburg v. Secretary of Health & Human Servs.*, 740 F.2d 100, 103 (1st Cir. 1983) (noting the general principle that the Social Security Act should be broadly construed "to carry our Congress's intent to provide medical expense coverage for all qualifying individuals"). To that end, Congress has demanded that any state restriction on drug distribution "provide such safeguards as may be necessary to assure that care and services . . . will be provided *in a manner consistent with the best interest of Medicaid's requirements.*" 42 U.S.C. § 1396c(a)(19) (West 1992) (emphasis added). Nowhere has Congress suggested that the federal Medicaid program can be used to further the interests of *non*-Medicaid recipients.

Pet. App. 68.

While conceding that the Maine Rx Program did not benefit anyone eligible to receive Medicaid benefits, the First

Circuit insisted that -- in determining whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and thus is preempted -- the absence of a "Medicaid purpose" in the Maine Rx Program was not fatal to the program:

> [W]e are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied. Thus, even if the district court's conclusion that "Maine can point to no Medicaid purpose in this new prior authorization requirement" is true, it does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program. We so no basis for inflicting the "strong medicine" of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program.

Pet. App. 12-13.

The First Circuit's analysis is faulty, on several grounds. First, the appeals court erred in adopting at the outset a strong presumption that State law was not preempted. The court dubbed preemption of a state law "strong medicine" that is "not casually to be dispensed." *Id.* at 10 (quoting *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 18 (1st Cir. 2000). The court added:

> This [presumption against preemption] is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism":

> "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one."

Id. (quoting *Wash., Dep't of Soc. & Health Servs. v. Bowen,* 815 F.2d 549, 557 (9th Cir. 1987)).

There is absolutely no support in this Court's case law for the appeals court's assertion that there is a particularly strong presumption against preemption in cases involving "cooperative federalism." To the contrary, "Pre-emption fundamentally is a question of congressional intent . . .," *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990), and there is no reason to assume that Congress is less likely to have intended to preempt State law in cases involving "cooperative federalism" than in other types of cases. Because States do not have any history of administering the Medicaid program without federal government involvement -- indeed, Medicaid is wholly a creature of federal law -- preemption of State laws in that area does not raise any federalism concerns and thus there is little reason to presume that Congress did not intend to preempt State laws that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Buckman Co. v. Plaintiffs' Legal Committee,* 121 S. Ct. 1012, 1017 (2001) (presumption against preemption is inapplicable in cases in which federalism concerns are not implicated). Accordingly, the appeals court erred in looking beyond the four corners of the Medicaid statute in determining whether the Maine Rx Program stands as an obstacle to the accomplishment of Congress's purposes.

Second, the appeals court erred factually in asserting that "the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose 'income and resources are insufficient to meet the costs of necessary medical services,' 42 U.S.C. § 196, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid." Pet. App. 13. To the contrary, the Program includes no means test, and thus *any* State resident who does not have health insurance coverage is eligible to participate. There is a nonfrivolous argument that low-income individuals who are not quite poor enough to qualify for Medicaid nonetheless are included within the broad class of individuals whom Congress intended to benefit in adopting the Medicaid program. But in the absence of a provision limiting participation to lower-income individuals, the Program cannot plausibly be deemed one that is designed to benefit the (broadly defined) intended beneficiaries of Medicaid.

Third, the Program threatens to impose real hardship on Medicaid recipients within Maine. The Program provides that prior authorization requirements will be imposed on all the products of a manufacturer that refuses to pay rebates. Me. Rev. Stat. Ann. tit. 22, § 2681(7). The record evidence is overwhelming that sales fall for all drugs placed on the prior authorization list, and that patients find it increasingly difficult to obtain their prescription drug of choice once that drug is placed on the list. Pressuring patients and their physicians to turn to lower-cost drugs (manufactured by companies willing to pay rebates) may result in lower short-term medical expenditures for a State, but Medicaid recipients inevitably suffer when they are (effectively) denied access to the drug they and their physician would have preferred. The Medicaid statutes include numerous

provisions to ensure that, when such denials occur, they are based on sound medical judgments. *See, e.g.*, 42 U.S.C. § 1396r-8(d)(2) (allowing States to deny Medicaid coverage for certain categories of non-essential drugs, such as drugs used for cosmetic purposes). Permitting a State to deny coverage for a drug that a physician wishes to prescribe for her Medicaid patients, solely because the drug manufacturer refuses to provide discount prices to wealthy State residents who lack insurance coverage, is wholly inconsistent with Congress's declared purpose of providing quality medical care to Medicaid-eligible individuals.

Indeed, the federal government, in the brief it filed at the petition stage of this case, stated as much. While arguing that Court review of the issues raised was premature, the United States stated unequivocally:

> Congress . . . has authorized States under certain conditions to impose prior authorization requirements on otherwise covered outpatient drugs. 42 U.S.C. 1396r-8(a) (1994 & Supp. V 1999); 42 U.S.C. 1396r-8(d)(5). Congress enacted those provisions so that States "would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy and quality of care." H.R. Rep. No. 881, 101 Cong., 2d Sess. 98 (1990). Congress assuredly did not intend that a State would use a requirement of prior authorization for the prescription of drugs for Medicaid beneficiaries in a manner that would burden the ability of Medicaid recipients to receive covered drugs without serving *some* purpose related to Medicaid.

Brief for United States at 11.

In sum, the Maine Rx Program stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Medicaid statute and thus is impliedly preempted.

II. THE MAINE RX PROGRAM VIOLATES THE COMMERCE CLAUSE

The Maine RX Program should be enjoined for the additional reason that its extraterritorial regulation of commerce violates the Commerce Clause. As did the First Circuit, the Court should reject Maine's argument that the "market participant" exception exempts the Program from Commerce Clause scrutiny.

A. The Program Is Not Exempted from Commerce Clause Scrutiny by the Market Participant Exception

Maine argued in the appeals court -- and may well choose to renew the argument here -- that regardless how much the Maine Rx Program burdens interstate commerce, the Program should be exempt from dormant Commerce Clause scrutiny because it falls within the "market participant" exception. Maine Court of Appeals Br. 30-35. That argument was rejected by the appeals court and continues to be without merit.

Under the "market participant" exception, a State or local government is not subject to dormant Commerce Clause limitations when its actions are not distinctively governmental in nature but rather it is acting in the role of a market

participant. *Camps Newfound/Owatonna, Inc. v. Town of Harrison,* 520 U.S. 564, 592 (1997). Thus, for example, a State that decides to pay a bounty for junked cars (as a means of encouraging the recycling of scrap metal) may show favoritism to in-state scrap metal processors without risking dormant Commerce Clause scrutiny. *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976). Similarly, a State that elects to operate a cement factory is not subject to dormant Commerce Clause constraints when it limits it sales to in-state customers. *Reeves, Inc. v. Stake,* 447 U.S. 429 (1980). Nor does the dormant Commerce Clause constrain a city engaged in the building trade that wishes to mandate that its contractors employ city residents. *White v. Massachusetts Council of Construction Employers, Inc.*, 460 U.S. 204 (1983).

The Court nonetheless has made clear that a State or local government may not rely on the market participant doctrine where it has used its leverage in a market in which it is a participant to impose burdens on commerce outside of that market. As the Court has explained:

> [T]he doctrine is not *carte blanche* to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is in contractual privity. . . . The limit of the market participant doctrine must be that it allows a State to impose burdens on commerce within the market in which it is a participant but allows it to go no further. The State may not impose conditions, whether by statute, regulation, or contract, that have a substantial regulatory effect outside of that particular market.

South-Central Timber Development, Inc. v. Wunnicke, 467 U.S. 82, 97 (1984) (plurality). The *Wunnicke* plurality determined that the market participant exception was inapplicable to Alaska's efforts to require those to whom it sold lumber to process the lumber within the State before shipping it elsewhere. *Id.* at 98. The plurality explained that the exception was inapplicable because Alaska was attempting to use its leverage in the market in which it was a participant (the timber sales market) "to exert a regulatory effect in the processing market, in which it is not a participant." *Id.*

There can be little doubt that the Maine Rx Program does not fit within the terms of the market participant exception. The Program -- an effort to regulate the price of all prescription drugs sold within the State -- is not the type of activity commonly thought of as proprietary in nature but rather is an example of "a State's acting in its distinctive governmental capacity," activity that the Supreme Court has repeatedly stated "is subject to the limitations of the negative Commerce Clause." *Camps Newfound/Owatonna*, 520 U.S. at 592.

Moreover, the market participant doctrine is wholly inapplicable when, as here, the State has played no role in creating the commerce which is alleged to have been improperly burdened. As Justice Stevens explained in *Alexandria Scrap*:

> It is important to differentiate between commerce which flourishes in a free market and commerce which owes its existence to a state subsidy program. Our cases finding that a state regulation constitutes an impermissible burden on interstate commerce all dealt with restrictions that adversely affected the operation of

> a free market. This case is unique because the commerce which Maryland has "burdened" is commerce which would not exist if Maryland had not decided to subsidize a portion of the automobile scrap-processing business.

Alexandria Scrap, 426 U.S. at 815 (Stevens, J., concurring). The market for prescription drug sales has existed in Maine for many years and will continue to exist regardless whether the Maine Rx Program ever takes effect. Accordingly, Maine may not invoke the market participant exception based on its alleged "participation" in a market which it played no role in creating.

Even conceding for the sake of argument that Maine is a "participant" in the Medicaid prescription drug market, it may not seek shelter in the market participant exception for its use of leverage in that market to regulate the sale of prescription drugs to residents ineligible for Medicaid. As the *Wunnicke* plurality explained, the market participant doctrine does not immunize a State that uses its leverage in a market in which it participates "to exert a regulatory effect" in a market in which it is not a participant. *Wunnicke,* 467 U.S. at 98 (plurality). If the doctrine were not "relatively narrowly defined" in this manner, it would have "the potential of swallowing up" dormant Commerce Clause limitation on a State's power to burden interstate commerce. *Id.*

In arguing for a contrary rule, Maine's reliance on *White* is misplaced. Maine argued that the Court invoked the market participant exception in *White* even though the City of Boston used its leverage in the market in which it participated (construction) to impose requirements (the hiring of city

residents) on its construction contractors in a market in which it was not a direct participant (the market for construction labor). Maine Br. 32. But *White* expressly disavowed Maine's characterization of the facts of that case; rather, the Court said that Boston was "a major participant" in the construction labor market. *White,* 460 U.S. at 211 n.7. The Court explained, "Everyone affected by the order [that at least 50% of those employed to work on the city's construction projects be city residents] is, in a substantial if informal sense, `working for the city.'" *Id.*

Inexplicably, Maine sought to turn *White*'s "in a substantial but informal sense" language to its own advantage. Maine argued:

> Here, all the prescription drugs consumed through the Maine Rx Program and Medicaid are "in a substantial but informal sense" for the benefit of the same population -- Maine residents without private insurance. Maine Rx beneficiaries will acquire the same prescription drugs, produced by the same manufacturers and sold by the same pharmacists, as their fellow residents on Medicaid. That Maine does not purchase the drugs in the Maine RX program is no more significant than the fact that Boston did not hire the laborers in *White*.

Maine Court of Appeals Br. 34. Maine's analogy to *White* makes absolutely no sense. *White* turned on the fact that the group for whose benefit Boston had acted (Boston residents hired to work on the city's construction contracts) could in substance be said to be "working for the city" in connection with the very market in which it was a market participant. For the two cases to be in any way analogous, Maine would

need to demonstrate that those affected by the Maine RX Program are in some "substantial if informal sense" a part of the Medicaid program. But, of course, those covered by the Maine Rx Program include all those who are *ineligible* to participate in Medicaid. Thus, *White* provides no support for Maine's position.

Indeed, the Court in *Wunnicke* explicitly rejected the broadened interpretation of *White* espoused by Maine. The Court explained that *White* turned on the fact that the hiring preference for city residents was limited to work that contractors were performing for Boston. *Wunnicke,* 467 U.S. at 97 n.10 (plurality). The market participant exception would have been inapplicable had Boston sought to extend its hiring preference "to the work force on all projects of any employer doing business with the city" (*id.*), even though Boston undoubtedly had just as much interest in encouraging employment of its residents on those other projects as it had in encouraging their employment in connection with projects being performed for the city. Similarly, that Maine has as great an interest in procuring low-cost prescription drugs for all its residents as it does in procuring such drugs for Medicaid recipients does not support Maine's efforts to invoke the market participant exception in this case.

Finally, *amici* note that a principal rationale for the market participant exception has been to permit States that act in a proprietary capacity to compete on an equal basis with private entities. As the Supreme Court explained in *Reeves*:

> [S]tate proprietary activities may be, and often are, burdened with the same restrictions imposed on private market participants. Evenhandedness suggests that, when acting as proprietors, States should similarly share existing freedoms from federal restraints, including the inherent limits of the Commerce Clause.

Reeves, 447 U.S. at 439. That rationale has no application to this case. Maine's operation of the Medicaid program does not even remotely resemble the types of "state proprietary activities" at issue in *Alexandria Scrap, Reeves,* or *White*, nor need Maine worry about its ability to compete on an equal footing with competing Medicaid providers. Accordingly, there can be no justification for immunizing Maine from the normal constraints imposed on State activity by the dormant Commerce Clause.

B. The Maine Rx Program Violates the Dormant Commerce Clause Because It Regulates Commerce Extraterritorially

The record is uncontested that virtually all prescription drugs sold in Maine were initially sold by drug companies to wholesalers in connection with transactions that took place wholly outside the State of Maine. Yet, the Maine Rx Program attempts to regulate such wholesale transactions by reducing the wholesale price by the amount of the rebate that manufacturers are required to pay to the State. Such State efforts to exert extraterritorial control over sales transactions lacking any significant nexus with the State constitute a *per se* violation of the Commerce Clause.

As the district court held, "bedrock principles concerning the territorial limits of a state's power" prohibit a State from attempting to "extend its authority to out-of-state manufacturers" in this manner. Pet. App. 64-65. This Court has repeatedly held that a State's efforts to control commerce occurring wholly outside the boundaries of the State are *per*

se invalid under the dormant Commerce Clause. The Court has explained:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions. First, the Commerce Clause precludes the application of a state statute to commerce that takes place outside of the State's borders, whether or not the commerce has effects within the State. [Citations omitted.] . . . Second, a statute that directly controls commerce wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989). In *Healy*, the Court struck down a Connecticut law that required liquor wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states, because the law had the inevitable impact of controlling wholesale prices in those neighboring States. *Id.* at 338.

Similarly, the Court struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935). Justice Brandeis wrote for the Court in that case:

> New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there. So much is not disputed. New

> York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or low ones.

Id. at 522.

Maine makes a half-hearted attempt to insist that it is not really regulating out-of-state drug sales at the wholesale level. Maine Opp. Br. 18 ("[T]he Maine Rx statute does not have th[e] effect [of regulating extraterritorial prices]. Simply put, it does not tie in-state prices to pricing elsewhere. It does not constrain manufacturers' pricing freedom."). That argument is without merit. It is uncontested that the amount of the rebate is tied directly to the volume of a manufacturer's drugs ultimately sold within Maine. Accordingly, each dollar of the rebate can be traced to a specific wholesale transaction that took place wholly outside Maine. Maine is correct, of course, that it does not dictate to manufacturers the precise wholesale price at which they must sell their drugs. But it cannot seriously be disputed that Maine is directly regulating those wholesale transaction: it is directing that the net wholesale price be reduced by the amount of the Maine Rx Program rebate.

The Commerce Clause does not, of course, constrain Maine's power to impose price controls on retail sales occurring within the State. But Maine has chosen not to pursue that path. Instead of imposing economic burdens on in-state pharmacists, it has attempted to impose those burdens on out-of-state drug manufacturers who, for the most part, have not engaged in any economic transactions within the State. Maine insists that the effect of its decision is not significantly different than if it had sought to regulate prices

at the retail level. We do not, of course, know the answer to that question. We do know, however, that the Supreme Court has stated in no uncertain terms that States' attempts to regulate extraterritorially in the manner adopted by Maine are *per se* invalid under the Commerce Clause.

Maine's effort to distinguish this case from *Healy* and other price control cases is unavailing. Both *Healy* and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), struck down as *per se* violations of the Commerce Clause state laws that required liquor wholesalers to affirm that their prices were no higher than the prices at which their products were sold in neighboring states. *Baldwin* struck down as a *per se* Commerce Clause violation a New York law that prohibited the sale in New York of milk which had been sold by milk producers in other states for less than New York's minimum producer price. Maine insists that *Baldwin, Healy*, and *Brown-Forman* are distinguishable because in each case, the challenged statute tied "the in-state price to those charged in another state." Maine Opp. Br. 18. Maine notes that the Maine Rx Program makes no effort to tie in-state and out-of-state prices. *Id.* That is no distinction at all, because (unlike the challenged statutes in *Baldwin, Healy,* and *Brown-Forman*) the Maine Rx Program operates directly on out-of-state prices. It was necessary for the plaintiffs in *Baldwin, Healy,* and *Brown-Forman* to demonstrate that in-state prices were tied to out-of-state prices because the challenged statutes did not on their faces purport to regulate out-of-state prices; it was only by demonstrating a tie-in that the plaintiffs could show that the States' regulation of in-state prices inevitably resulted in the regulation of out-of-state prices. Because the Maine Rx Program directly regulates out-of-state wholesale prices, there is no need for PhRMA to demonstrate a tie-in between

in-state and out-of-state prices,[3] and thus *Baldwin, Healy,* and *Brown-Forman* cannot be distinguished on that basis.

Maine also argued in the appeals court that, even if the extraterritoriality of State regulation can raise Commerce Clause concerns, such concerns can never amount to *per se* violations of the dormant Commerce Clause. Maine Court of Appeals Br. 42-50. That argument utterly fails to address the Court's language in *Healy* and similar cases that "the Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside the State's borders, whether or not the commerce has effects within the State." *Healy,* 491 U.S. at 336 (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)).

The United States warns against the allegedly dire consequences of adpting PhRMA's view of the Commerce Clause:

> Indeed, petitioner's broad reasoning would condemn a wide variety of permissible state regulations that may affect the conduct of out-of-state manufacturers for the in-state sale of defective or unreasonably dangerous drugs or requiring that all automobiles sold in-state meet state emissions standards.

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[3] Because the Rx Program rebate is tied to the Medicaid rebate and the Medicaid rebate determines a nationwide price for prescription drugs sold under the Medicaid program, a strong case can be made nonetheless that the Rx Program rebate *is* directly tied to out-of-state prescription drug prices.

U.S. Br. 17. The United States's concerns are not well founded. A State is free to regulate sales of goods within its borders. Such regulation may encompass not only the sales price but also the quality of goods sold; if the goods are defective, the State may sanction all parties responsible for bringing about the sale of defective goods. But what it may not do is regulate sales transactions that take place outside its borders, regardless whether the goods sold eventually make their way into the State.

Maine also argued that *Healy* and similar cases are outdated and have been replaced by a more modern Commerce Clause jurisprudence that eschews a *per se* approach to dormant Commerce Clause issues. In support of that proposition, Maine cited several Supreme Court decisions that have focused on discrimination against interstate commerce as the principal concern of the dormant Commerce Clause. *See, e.g.*, Maine Appeals Court Br. at 43 (citing *CTS Corp. v. Dynamics Corp. of America,* 481 U.S. 69, 87 (1987), for the proposition that "[t]he principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce"). Noting that the Maine Rx Program does not discriminate between in-state and out-of-state drug manufacturers (indeed, there are no in-state manufacturers), Maine argued that the Program should not be subjected to *per se* invalidation. *Id.* 42-50.

But none of the case law cited by Maine indicates that discrimination against interstate commerce should be the *sole* ground for finding State regulation *per se* invalid under the dormant Commerce Clause, or that *Healy* and *Brown-Forman* (which were decided in 1989 and 1986, respectively) are no longer good law. Indeed, in a more recent decision, the Supreme Court gave a ringing endorsement to *per se*

invalidity rules outside of the context of discrimination against interstate commerce. In *Quill Corp. v. North Dakota,* 504 U.S. 298 (1992), the State of North Dakota sought a declaratory judgment that out-of-state mail-order companies shipping goods into North Dakota were required to collect and remit use tax based on the value of the goods shipped. The Supreme Court held that any effort by a State to collect such use taxes from mail order companies would be a *per se* violation of the dormant Commerce Clause where the company had no connection with the taxing state other than that its goods eventually made their way into the State. *Quill Corp.*, 504 U.S. 309-318. While noting that such State tax collection efforts would in no way discriminate against interstate commerce, the Court held that the dormant Commerce Clause also "bars state regulations that unduly burden interstate commerce." *Id.* at 312. In establishing a *per se* rule that State tax collection efforts against out-of-state mail order companies would, in fact, "unduly burden interstate commerce," the Court recognized that such a rule "appears artificial at its edges" because, for example, "Whether or not a State may compel a vendor to collect a sales or use tax may turn on the presence in the taxing State of a small sales force, plant or office." *Id.* at 315. The Court nonetheless chose to adopt a *per se* rule because any "artificiality . . . is more than offset by the benefits of a clear rule." *Id.* The Court added:

> A bright-line rule in the area of sales and use taxes also encourages settled expectations and, in doing so, fosters investment by businesses and individuals.

Id. at 316.

Quill Corp.'s rationale is equally applicable here. The Court has long maintained a clear distinction between State efforts to control interstate commerce that occurs within the State's boundaries and efforts to control interstate commerce outside those boundaries. The latter have repeatedly been held *per se* invalid under the dormant Commerce Clause. It may be true that there will be cases in which this distinction appears somewhat artificial. It may be that Maine could accomplish a major portion of what the Rx Program seeks to accomplish without resorting to regulation of wholesale drug sales occurring wholly outside the State. Nonetheless, the clear prohibition against extraterritorial application of State regulations has stood the test of time; it provides a bright-line rule that "encourages settled expectations" and "fosters investment." That rule should not be lightly cast aside.

Amici note, moreover, that if Maine is free to regulate wholesale drug prices extraterritorially, then other States would be free to attempt to regulate retail prices in Maine. A State in which drug manufacturers maintain their principal place of business might, for example, seek to maintain minimum retail drug prices in Maine, assuming that they possessed market leverage that they could use for that purpose. By prohibiting States from regulating extraterritorially, the dormant Commerce Clause guards against that possibility.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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